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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/827,484	04/19/2004	Makarand Gore	200315586-1	3315

22879 7590 02/11/2008
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INTELLECTUAL PROPERTY ADMINISTRATION
FORT COLLINS, CO 80527-2400

EXAMINER

KISHORE, GOLLAMUDI S

ART UNIT	PAPER NUMBER
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1612

NOTIFICATION DATE	DELIVERY MODE
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02/11/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/827,484	Applicant(s) GORE, MAKARAND	
	Examiner Gollamudi S. Kishore, Ph.D	Art Unit 1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11-26-07.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-59 is/are pending in the application.
- 4a) Of the above claim(s) 6 and 17-54 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 7-16, 55 and 56 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>1-12-05</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's election without traverse of Group I and species I (a) in the reply filed on 11-26-07 is acknowledged.

Claims included in the prosecution are 1-5, 7-16 and 55-56.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 4, 5 and 11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 4 recites "wherein said edible vehicle further comprises a solvent. It is unclear what it means since the parent claim 3 recites either water or alcohol and these are solvents. Is the solvent recited a solvent for the lipids or the active agent?

It is unclear whether the limitation in parenthesis in claim 5 is indeed the limitation.

The claimed compositions are aqueous compositions. Therefore, it is unclear as to what applicant intends to convey by 'drying agent' in claim 11. What does that dry?

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-5, 7-8, 10-15 and 55-56 are rejected under 35 U.S.C. 102(b) as being anticipated by Hsu (5,653,996).

Hsu discloses liposomal formulations containing phosphatidylcholines and phosphatidylglycerol in a buffer solution. The active agents include water insoluble active agents. The compositions further contain a surfactant, Tween which is considered as a solvent (abstract, col. 4, line 52 through col. 6, line 35, col. 9, lines 28-35, examples and claims). Although Hsu does not specifically teach the viscosity of the compositions, since instant claims only recite that the viscosity be less than 5 centipoise, it is the examiner's position, in the absence of showing otherwise, that the compositions of Hsu possess the claimed viscosity. The intended use has no significance in composition claims.

6. Claims 1-5, 7-15 and 55-56 are rejected under 35 U.S.C. 102(b) as being anticipated by Schlossmann (4,976,964).

Schlossmann discloses liposomal dispersions of Nifedipine and dihydropyridines. The phospholipids include phosphatidylcholine and phosphatidylserine. The formulations include glycerol (solvent) and buffers. The sizes of the liposomes are 50-100 nm (Col. 3, lines 20-51 and examples). Although Schlossmann does not specifically teach the viscosity of the compositions, since instant claims only recite that the viscosity be less than 5 centipoise, it is the examiner's position, in the absence of

showing otherwise, that the compositions of Schlossmann possess the claimed viscosity. The intended use has no significance in composition claims.

7. Claims 1-3, 5, 7-8, 12-15 and 55-56 are rejected under 35 U.S.C. 102(b) as being anticipated by Waldrep (5,958,378).

Waldrep discloses liposomal formulations containing cyclosporin. The phospholipids include phosphatidylcholine (abstract, col. 5, lines 25-36, Examples and claims). Although Waldrep does not specifically teach the viscosity of the compositions, since instant claims only recite that the viscosity be less than 5 centipoise, it is the examiner's position, in the absence of showing otherwise, that the compositions of Waldrep possess the claimed viscosity. The intended use has no significance in composition claims.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hsu or Schlossmann or Waldrep cited above.

The teachings of Hsu, Waldrep and Schlossmann have been discussed above. It is unclear from these references whether the compositions contain claimed amounts of vehicle, vesicle forming component and the payload. Assuming that the amounts are

different, it is deemed obvious to one of ordinary skill in the art to use desired amounts of the phospholipids to form required population of liposomes and suspend them in a suitable amount of vehicle. Since the amounts of the active agent depend upon the condition to be treated, this parameter is deemed to be a variable parameter.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gollamudi S. Kishore, Ph.D whose telephone number is (571) 272-0598. The examiner can normally be reached on 6:30 AM- 4 PM, alternate Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Krass Frederick can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

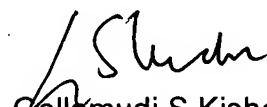
Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

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Gollamudi S Kishore, Ph.D
Primary Examiner
Art Unit 1612

GSK